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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,663	07/10/2002	**Armin Prasch**	3671/OK437	6944

7590 02/26/2008

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EXAMINER	
AHMED, HASAN SYED	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
02/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/089,663	PRASCH ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

- Receipt is acknowledged of applicants' amendment to the claims, amendment to the specification, remarks, RCE and English translation of DE 198 49 589, all filed on 17 December 2007.
- The 35 USC 112, 1st paragraph rejections as to the term "depot" are hereby withdrawn in view of the amendment.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the specification does not teach how to make a medicament formulation comprising ceramic granules or calcium phosphate. No examples are provided.

2. Claims 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the specification does not teach how to make a bone replacement implant. No examples are provided.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18-25, 28-31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heath, et. al. (WO 97/44015).

Heath, et. al. teach a granulated fibrin tissue adhesive formulation (*see* col. 3, lines 28-39). The disclosed formulation is comprised of:

- the blood plasma protein of instant claim 18 (*see* page 2, line 35);
- the thrombin of instant claim 18 (*see* page 2, line 35);
- the carrier granules of instant claim 18 (*see* page 3, lines 9-18);
- the active agent of instant claim 18 (*see* page 2, line 35);
- the carrier system of instant claims 19-21 (*see* page 3, lines 9-18);
- the granule comprised of an internal core of mannitol and external layer plasma protein of instant claims 22 and 23 (*see* page 3, lines 32-36);
- the substance which promotes wound healing of instant claim 28 (*see* page 2, line 35);
- the topical, parenteral, and transdermal routes of administration of instant claims 29-31 (see Example);
- the particle size (up to 50 μm in diameter) of instant claim 18 (*see* page 3, line14); and
- the process of producing a depot medicament of instant claim 34 (*see* page 3, lines 19-25).

Heath, et. al. explain that a granulated blood plasma protein medicament formulation formed by spray-drying is beneficial because it provides, "...good flow properties, enhanced, effective delivery to the active site, and dissolution only at the site, not in the delivery system." *See* page 3, lines 1-7.

Although the Heath, et. al. reference does not disclose the fluidized bed drying step of instant claim 18, the process of fluidized bed drying recited in claim 18 is not essential to a determination of patentability of the formulation disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a granulated blood plasma protein medicament formulation, as taught by Heath, et. al. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a formulation because of good flow properties, enhanced, effective delivery to the active site, and dissolution only at the site, as explained by Heath, et. al.

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-25, 28-31 and 34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 13 of U.S. Patent No. 6,596,318 (U.S. '318). Although the conflicting claims are not identical, they are not patentably distinct from each other because U.S. '318 claims a granulated blood plasma protein medicament formulation (*see* claim 1) produced by fluidized bed drying (*see* col. 16).

Although U.S. '318 does not claim an active ingredient, use of active ingredients with plasma protein medicament formulations was known in the art at the time the instant application was filed, as evidenced by Heath, et al. (*see* 103 rejection, above).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a granulated blood plasma protein medicament formulation, as taught by U.S. '318 in view of Heath, et. al. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a formulation because of good flow properties, enhanced, effective delivery to the active site, and dissolution only at the site, as explained by Heath, et. al.

* * * * *

Response to Arguments

Applicant's arguments filed on 17 December 2007 have been fully considered but they are not persuasive.

35 USC 112, 1st Paragraph

Applicants argue that the material incorporated by reference from DE 198 49 589 obviates the 35 USC 112, 1st paragraph rejection over claims 26, 27, 32, and 33 (*see* remarks, paragraph bridging pages 6 and 7).

Examiner respectfully submits that the incorporated material does not teach how to make a medicament formulation comprising ceramic granules or calcium phosphate; nor does not teach how to make a bone replacement implant.

*

35 USC 103

Applicants argue that the instant application is distinguished from the prior art by a difference in particle size. *See* remarks, pages 7-8.

In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Examiner respectfully submits that the Heath reference teaches particle size up to 50 µm in diameter, which directly overlaps with the particle range claimed in instant claim 18.

*

Double Patenting

Applicants argue that the '318 patent does not claim an active ingredient. *See* remarks, page 9.

Examiner respectfully submits that use of active ingredients with plasma protein medicament formulations was known in the art at the time the instant application was filed, as evinced by Heath, et al. (*see* 103 rejection, above).

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1618

/Humera N. Sheikh/
Primary Examiner, Art Unit 1618